

Amendments to the Claims:

The following listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A controlled drug release electrode system comprising an electrode bearing a bi-layer coating, the bi-layer coating comprising a doped electroactive electro-active polymer layer on the electrode having an ionic exchangeable releasable dopant thereon and an effective conforming thickness of a water insoluble film forming a water-insoluble overlayer on the doped electro-active polymer layer, the doped electro-active polymer layer comprising an electro-active polymer doped with an ionic exchangeable releasable dopant and the overlayer being substantially impermeable to said dopant.
2. (Currently Amended) The electrode system of claim 1 wherein said ~~effective conforming thickness~~ overlayer is of a thickness sufficient to be substantially impermeable to said dopant.
3. (Currently Amended) The system of claim 1 wherein said ~~insoluble film~~ forming overlayer comprises a polymer.
4. (Currently Amended) The system of claim 3 wherein said polymer comprises poly(vinyl butyral), [[nafion]], sulfonated polytetrafluoroethylene, or poly(vinyl acetate).
not in spec
5. (Original) The system of claim 4 wherein the poly(vinyl acetate) is at the most 88% hydrolyzed.
6. (Original) The system of claim 4 wherein the poly(vinyl acetate) is less than or equal to 40% hydrolyzed.
7. (Withdrawn) A process for preparing a controlled drug release electrode system, said system comprising an electroactive polymer having an ionic exchangeable dopant thereon and an effective conforming thickness of a water insoluble film forming overlayer substantially impermeable to said dopant thereon, said process comprising the effective application of said film forming overlayer in an adherent fashion to said polymer.
8. (Withdrawn) The process of claim 7 wherein said application process is selected from the group consisting of dipping, coating, printing, spraying and vapor deposition of said film forming overlayer to said polymer.

9. (Withdrawn) The process of claim 7 wherein said film forming overlayer is adherent to said polymer.

10. (Withdrawn) The process of claim 8 wherein said film forming overlayer comprises a polymer.

11. (Withdrawn) The process of claim 8 wherein said polymer comprises homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

12. (Withdrawn) The process of claim 11 wherein said polymer comprises polypyrrole.

13. (Withdrawn) The process of claim 10 wherein said polymer comprises poly(vinyl butyral), nafion, or poly(vinyl acetate).

14. (Withdrawn) A method for treating patients using a controlled drug release electrode system, said system comprising an electroactive polymer having an ionic exchangeable dopant thereon and an effective conforming thickness of a water insoluble film forming overlayer substantially impermeable to said dopant, said method comprising contacting said patient with said electrode system and applying an effective potential to said electrode system whereby said drug is made effectively available to the patient.

15. (Withdrawn) The method of claim 14 wherein said film forming overlayer comprises a hydrophobic polymer.

16. (Withdrawn) The method of claim 15 wherein said overlayer is selected from the group consisting of poly(vinyl butyral), poly(vinyl acetate), or Nafion.

17. (Withdrawn) The method of claim 14 wherein said electroactive polymer comprises homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

18. (Withdrawn) The method of claim 17 wherein said electroactive polymer is polypyrrole.

19. (Withdrawn) A process of using a polymeric material as a controlled drug delivery system comprising the use of a polymer bilayer containing drug molecules to impede the spontaneous release of said drug molecules when no electrochemical stimulus is applied.

20. (Withdrawn) The process of claim 19 wherein the polymer bilayer comprises an electroactive polymer and a second polymer layer, where the second polymer layer is applied to the top of the electroactive polymer.

21. (Withdrawn) The method of claim 20 wherein the second polymer layer is made of hydrophobic material and is crosslinked.

22. (Withdrawn) The method of claim 20 wherein the second polymer layer is selected from the group consisting of poly(vinyl butyral), Nafion and poly(vinyl acetate).

23. (Withdrawn) The method of claim 20 and 22 wherein the electroactive polymer is homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

24. (Withdrawn) The method of claim 23 wherein said electroactive polymer is polypyrrole.

25. (Currently Amended) An article of manufacture comprising a controlled drug release electrode system as set forth in claim 1 ~~comprising an electroactive polymer having an ionic exchangeable dopant thereon and additionally an effective conforming thickness of a water insoluble film forming overlayer substantially impermeable to said dopant.~~

26. (Currently Amended) The article of manufacture of claim 25 where said article of manufacture is placed in contact with a patient's skin.

27. (Original) The article of manufacture of claim 26 wherein an effective potential is applied to said electrode wherein said potential causes the release of said drug, making said drug effectively available to the patient.

28. (Currently Amended) The ~~method~~ article of manufacture of claim 25 wherein said ~~film forming overlayer~~ overlayer comprises a polymer made from hydrophobic material which is crosslinked.

29. (Currently Amended) The ~~method~~ article of manufacture of claim 28 wherein said ~~electroactive~~ electro-active polymer comprises homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

30. (Currently Amended) The ~~method~~ article of manufacture of claim 29 wherein said ~~electroactive~~ electro-active polymer comprises polypyrrole.

31. (Withdrawn) A process of creating an electrochemical responsive controlled drug delivery system comprising loading a film of an electroactive polymer with an active ingredient, applying a second polymer layer to said electroactive polymer loaded with an active ingredient, and allowing said second polymer layer to dry.

32. (Withdrawn) The process of claim 31 where said electroactive polymer comprises homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

33. (Withdrawn) The process of claim 32 wherein said electroactive polymer comprises polypyrrole.

34. (Withdrawn) The process of claim 33 wherein said electroactive polymer is produced by depositing polypyrrole onto a stainless steel electrode by utilizing a constant potential from an aqueous solution comprising a pyrrole, a salt of an anionic or cationic active ingredient, and a dopant.

35. (Withdrawn) The process of claims 31 wherein the second polymer layer is poly(vinyl butyral).

36. (Withdrawn) The process of claim 35 wherein the second polymer layer is allowed to dry at about room temperature.

37. (Withdrawn) The process of claims 31 wherein the second polymer layer is nafion.

38. (Withdrawn) The process of claim 37 wherein the second polymer layer is allowed to dry at about 150° C for 1 hour.

39. (Withdrawn) The process of claim 31 wherein the second polymer layer is poly(vinyl acetate).

40. (Withdrawn) The process of claim 39 wherein the second polymer layer is allowed to dry at room temperature.

41. (Withdrawn) The process of claim 42 wherein the second polymer layer is thermally crosslinked in a vacuum for about 30 minutes at 70° C and then for 30 minutes at 150°C.

42. (Withdrawn) The process of claim 41 wherein the poly(vinyl acetate) is less than 88% hydrolyzed.

43. (Withdrawn) The process of claim 42 wherein the poly(vinyl acetate) is about 40% hydrolyzed.

44. (Currently Amended) A dopant controlled release system comprising a bi-layer coating on an electrode, the bi-layer coating comprising (1) a layer of an electroactive electro-active polymer, the layer having a first surface in contact with the electrode and a second surface opposite the first surface, the electro-active polymer having an ionic exchangeable releasable dopant thereon, and (2) and an overlayer on the second surface that inhibits to lessen the spontaneous release of said dopant.

45. (Original) The system of claim 44 wherein the overlayer is made of a hydrophobic material.

46. (Original) The system of claim 45 wherein the overlayer is highly networked.

47. (Original) The system of claim 46 wherein the overlayer is highly networked due to crosslinking.

48. (Currently Amended) The system of claim 45 wherein the overlayer is chosen from the group consisting of poly(vinyl butyral), poly(vinyl acetate), and [[nafion]] sulfonated polytetrafluoroethylene.

49. (Original) The system of claim 48 wherein said electroactive polymer comprises homopolymers and copolymers of polypyrrole, N-substituted pyrrole and C-substituted pyrrole.

50. (Currently Amended) The system of claim 49 wherein said electroactive electro-active polymer comprises polypyrrole.

51. (Currently Amended) The [[method]] system of claim 45 wherein said dopant is a biologically active ingredient.

52. (Currently Amended) The [[method]] system of claim 51 wherein said biologically active ingredient is a pharmaceutical compound.

53. (Currently Amended) The [[method]] system of claim 52 wherein said pharmaceutical compound is selected from the group consisting of nutritional supplements, anti-inflammatory agents(e.g. NSAIDS such as s-ibuprofen, ketoprofen, fenoprofen, indomethacin, meclofentamate, mefenamic acid, naproxen, phenylbutazone, piroxicam, tolmetin, sulindac, and dimethyl sulfoxide), antipyretics, anesthetics including benzocaine, pramoxine, dibucaine, diclonine, lidocaine, mepiracaine, prilocaine, and tetracaine; demulcents; analgesics including opiate analgesics, non-opiate analgesics, non-narcotic analgesics including acetaminophen and astringent including calamine, zinc oxide, tannic acid, Hamamelis water, zinc sulfate; natural or synthetic steroids including triamcinolone, acetone, prednisone, beclomethasone dipropionate; asthmatic drugs including terbutaline sulfate, albuterol, leukotriene receptor antagonists; electrolytes, metals and minerals;

antianxiety and antidepressant agents; antimicrobial and antiviral agents; antihistamines; immune-suppression agents; cholesterol-lowering agents; cardiac and high-blood pressure agents and mixtures thereof.

54. (Newly Presented) The electrode system of claim 1 wherein said overlayer is substantially free of the dopant.

55. (Newly Presented) The electrode system of claim 1 wherein said overlayer is substantially free of any dopant.

56. (Newly Presented) The electrode system of claim 25 wherein said overlayer is substantially free of the dopant.

57. (Newly Presented) The electrode system of claim 25 wherein said overlayer is substantially free of any dopant.

58. (Newly Presented) A coated substrate comprising a bi-layer coating on a substrate, the bi-layer comprising a doped electro-active polymer layer having a first surface in contact with the substrate and a second surface opposite the first surface, and water-insoluble overlayer on the second surface of the doped electro-active polymer layer, the doped electro-active polymer layer comprising an electro-active polymer doped with an ionic exchangeable releasable dopant and the overlayer being substantially impermeable to said dopant.

Conclusion

In view of the foregoing, prompt and favorable reconsideration of this Amendment is respectfully requested.

Respectfully submitted,



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